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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/802,166	03/17/2004	James Robert Schwartz	9184M	4150

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EXAMINER

ARNOLD, ERNST V

ART UNIT	PAPER NUMBER
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1616

MAIL DATE	DELIVERY MODE
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10/10/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/802,166	Applicant(s) SCHWARTZ ET AL.	
	Examiner Ernst V. Arnold	Art Unit 1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 August 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3,4 and 7-25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 3, 4, 7-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 2, 5 and 6 have been cancelled. Claims 1, 3, 4 and 7-25 are pending and under examination. Applicants amendments have necessitated a new ground of rejection. Accordingly, this action is FINAL.

Comment: With respect to the new limitation in claim 1 of "the ratio of surfactant to zinc-containing layered material is greater than or equal to 2 to 1", the examiner notes that in Example 41 sodium lauryl sulfate is present at 4.00 and zinc hydroxy sulfate is present at 2.00. Thus the limitation is supported.

Withdrawn rejections:

Claims 7 and 8 were rejected under 35 U.S.C. 112, second paragraph. Applicant has amended the claims and the Examiner withdraws the rejection.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 3, 4 and 7-25 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 1 introduces new matter as the claims recites the limitation "...from about 10 % to about 50 % of a surfactant" There

is no support in the specification for this range. This limitation was not described in the specification as filed, and person skilled in the art would not recognize in the applicant's disclosure a description of the invention as presently claimed. The specification discloses the ranges of from about 2 % to about 50 % and from about 10 % to about 25 % on page 8 but does not describe the range of from about 10 % to about 50 %. There is no guidance in the specification to select this range. It is therefore a new concept. Consequently, it is the Examiner's position that the disclosure does not reasonably convey that the inventor had possession of the subject matter of the amendment at the time of filing of the instant application.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3, 4, 7-13, and 18-25 remain/are rejected under 35 U.S.C. 102(b) as being anticipated by Gavin et al. (WO 01/00151) as evidenced by the Mineral Willemite.

The Examiner sought guidance from the specification on the definition of a zinc-containing layered material. Applicant defines a zinc-containing layered material (Page 5, lines 11-16) as:

Many ZLM's occur naturally as minerals. Common examples include hydrozincite (zinc carbonate hydroxide), basic zinc carbonate, aurichalcite (zinc copper carbonate hydroxide), rosasite (copper zinc carbonate hydroxide) and many related minerals that are zinc-containing. Natural ZLM's can also occur wherein anionic layer species such as clay-type minerals (e.g., phyllosilicates) contain ion-exchanged zinc gallery ions. All of these natural materials can also be obtained synthetically or formed in situ in a composition or during a production process.

Gavin et al. disclose a topical anti-dandruff composition for treating microbes comprising from 0.001 to 10% zinc pyrithione; from 0.001 to about 10% of a zinc salt and an anionic deterative surfactant for a topical carrier thus reading on instant claims 1-3, 7 and 8 (Claim 1). The zinc salt can be zinc silicate, which is also known as the mineral willemite (Claim 6). Since Applicant teaches that a non-limited list of natural minerals containing zinc can also be obtained synthetically or formed in situ and Gavin et al. disclose zinc silicate, which has the same common formula for the mineral Willemite, then the zinc silicate of Gavin et al. would inherently have the same relative zinc lability of greater than about 15% to greater than about 20% and to greater than about 25% and thus meet the limitations of instant claims 1, 12 and 13. The pH of the compositions ranges from about 2 to about 10 and most preferably from about 5.5 to about 7.5 thus within the scope of instant claims 9-11 (Page 7, lines 7-9). The concentration of the anionic surfactant ranges from about 5% to about 50% by weight of the composition consequently reading on instant claim 4 (Page 8, lines 10-16). The addition of cationic deposition polymers (instant claim 18) is anticipated (Page 20, lines 30-34-page 25, line 30). The addition of conditioning agents (instant claim 19) is anticipated (Page 35, line 12- page 47, line 16). Suspending or thickening agents are

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anticipated and crystalline suspending agents are preferred thus reading on instant claims 20-22 (Page 18, line 27-page 20, line 28) Methods pertaining to treating microbial infections preferably related to dandruff and treating athlete's foot, a contagious fungal infection, are provided hence anticipating instant claims 23-25 (Claim 9).

Response to arguments:

Applicant asserts that Willemite is not a layered material but has not provided any evidence to support this assertion. The Examiner maintains that Willemite is a layered material as evidenced by the crystallographic data (page 2 of 16), which states:

Crystallography of Willemite

Crystal System: Trigonal Class (H-M): 3 - Rhombohedral Space Group: $R\bar{3}$ Cell Parameters: $a = 13.93\text{\AA}$, $c = 9.31\text{\AA}$

Ratio: $a:c = 1 : 0.668$ Unit Cell Volume: $V 1,564.53\text{\AA}^3$ (Calculated from Unit Cell) Z: 18

Morphology: Blocky, hexagonal, barrel-shaped crystals, often with rounded terminations (Franklin area); commonly acicular in clusters to radial-fibrous aggregates; long-prismatic, hexagonal, doubly-terminated crystals; **layered**,

With respect to the new limitation of the ratio of surfactant to zinc-containing layered material is greater than or equal to 2 to 1, Gavin disclose this range. For example, when the surfactant is 20 wt % and the zinc salt (zinc silicate) is 10 wt % and then the 2 to 1 ratio is anticipated. Applicant's arguments are not persuasive and the rejection is maintained.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1, 3, 4 and 7-25 remain/are rejected under 35 U.S.C. 103(a) as being unpatentable over Iwai et al. (EP 1145707A1) in view of Gavin et al. (WO 01/00151).

Applicant claims a composition comprising a zinc-containing layered material, a surfactant and pyrrithione and methods of treating microbial infections and dandruff.

Determination of the scope and content of the prior art

(MPEP 2141.01)

The reference of Gavin et al. is discussed in detail above and that discussion is hereby incorporated by reference.

Iwai et al. teach compositions for external use comprising: 0.01-20 wt% of a zinc compound, such as basic zinc carbonate; 0.01-20 wt% of a thiol compound; and an anionic surfactant (Claims 1, 2, 4, 6 and 7 and page 8 lines 4 and 46 bridging page 9 line 9, for example). It is the Examiner's position that the basic zinc carbonate taught by Iwai et al. would have the same level of zinc lability as instantly claimed (claims 1, 12 and 13) in the absence of evidence to the contrary. Iwai et al. teach adding cationic surfactants (page 9, lines 4-9). Iwai et al. teach adding thickeners (suspending agents) such as gelatin, guar gum and methyl cellulose (page 9, lines 55-58). Iwai et al. teach the addition of various oils (conditioning agents) to the composition (page 8, lines 5-45).

**Ascertainment of the difference between the prior art and the claims
(MPEP 2141.02)**

1. Iwai et al. do not expressly teach a composition wherein the thiol compound is pyrithione.
2. Iwai et al. do not expressly teach a composition wherein the surfactant is present from about 2 % to about 50 %.
3. Iwai et al. do not expressly teach a composition wherein the pH is greater than about 6.5; wherein the pH is from about 6.8 to about 9.5 or the narrow range of 6.8 to about 8.5.
4. Iwai et al. do not expressly teach a method of treating microbial infections, fungal infections or dandruff with the composition.

Finding of prima facie obviousness

Rational and Motivation (MPEP 2142-2143)

1. It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to add zinc pyrithione, as suggested by Gavin et al., to the composition of Iwai et al. and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because Iwai et al. suggest adding thiol compounds to the composition but not specifically pyrithione and Gavin et al. cure this deficiency by teaching that zinc pyrithione is suitable for external compositions.

2. It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to add an anionic surfactant from about 2 % to about 50 %, as suggested by Gavin et al., to the composition of Iwai et al. and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because Iwai et al. suggest adding anionic surfactants to the composition but does not teach the amount. Gavin et al. cure this deficiency by providing the teaching on the amount of anionic surfactant to add to the composition.

3. It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to make the composition wherein the pH is greater than about 6.5; wherein the pH is from about 6.8 to about 9.5 or the narrow range of 6.8 to about 8.5 as suggested by Gavin et al., to the composition of Iwai et al. and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because Iwai et al. does not teach the pH of the composition and Gavin et al. cure this deficiency by providing the teaching on the pH for the composition.

4. It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to use the composition of Iwai et al. in a method of treating microbial and fungal infections as well as dandruff, as suggested by Gavin et al., and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because Iwai et al. suggest the composition is useful for external use but not for those methods instantly claimed and Gavin et al. cure this deficiency by providing the teaching on the types of methods such a composition is useful for.

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. (*In re Opprecht* 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA) 1976).

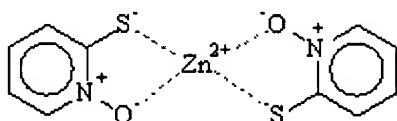
In light of the forgoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a).

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of

ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Response to arguments:

Applicant asserts that pyrrhithione is not a thiol. The Examiner cannot agree. As can be seen in the structure of zinc pyrrhithione, pyrrhithione has a free thiol for binding to zinc.



Applicant's arguments are not persuasive and the rejection is maintained.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1, 3, 4 and 7-25 remain/are rejected under 35 U.S.C. 103(a) as being unpatentable over Gavin et al. (WO 01/00151) in view of Bhat et al. (WO 96/25913).

Applicant claims a composition comprising a zinc-containing layered material, a surfactant and pyrithione and methods of treating microbial infections and dandruff.

Determination of the scope and content of the prior art
(MPEP 2141.01)

The reference of Gavin et al. is discussed in detail above and that discussion is hereby incorporated by reference.

Bhat et al. teach personal care product compositions comprising a surfactant and monophasic zinc hydroxycarbonate in an amount of 0.1-20 % by weight (Claims 1 and 2). The structure of the zinc compound is $Zn_5(OH)_6(CO_3)_2 \cdot X H_2O$ where X varies between 0 and 4 (Page 6, lines 23-27). When X=0 then the same formula for basic zinc carbonate as disclosed by Applicant is taught (see instant specification page 6, line 6). It is the Examiner's position that the basic zinc carbonate taught by Bhat et al. would have the same level of zinc lability as instantly claimed (claims 1, 12 and 13) in the absence of evidence to the contrary. Bhat et al. teach the surfactant can be sodium lauryl sulphate, an anionic surfactant, in the amount of 2.5% (Page 12, line 10).

Ascertainment of the difference between the prior art and the claims

(MPEP 2141.02)

Gavin et al. do not expressly teach a composition wherein the zinc salt is a zinc layered material such as basic zinc carbonate.

Finding of prima facie obviousness

Rational and Motivation (MPEP 2142-2143)

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to add basic zinc carbonate, as suggested by Bhat et al., to the composition of Gavin et al. and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because Gavin et al. broadly teach adding zinc salts, including the mineral zinc silicate, to the composition but not other zinc layered materials instantly claimed. Bhat et al. cure this deficiency by teaching that basic zinc carbonate is suitable for personal care compositions. Moreover, Bhat et al. teach the antimicrobial properties of basic zinc carbonate which would aid the topical composition of Gavin et al. for treating microbes (Abstract and claim 7).

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. (*In re Opprecht* 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA) 1976).

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In light of the forgoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a).

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Response to arguments:

Applicant asserts that the new limitation of the ratio of surfactant to zinc-containing layered material is greater than or equal to 2 to 1 is not taught by Bhat. However, Gavin disclose this ratio as discussed above. Applicant's arguments are not persuasive and the rejection is maintained.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ernst V. Arnold whose telephone number is 571-272-8509. The examiner can normally be reached on M-F (6:15 am-3:45 pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ernst Arnold
Patent Examiner
Technology Center 1600
Art Unit 1616

A handwritten signature in black ink, appearing to read 'Johann R. Richter', with a large, stylized loop at the beginning.

Johann R. Richter
Supervisory Patent Examiner
Technology Center 1600